

REMARKS/ARGUMENT

Status of the Claims

Claims 25, 32-34 and 36-39 and 41 were rejected in the last Official Action. Claims 1-12, 25, 31 and 40 are canceled. New claims 42 and 43 have been added. Claims 13-24, 26-30 and 35 are withdrawn. The support for new claim 42 may be found, for example, on page 13, first paragraph and in the first full paragraph, page 14 of the PCT publication. Support that the "lipid" is free of unhealthy fatty acids is clear because of its composition of fatty acid moieties. The specification talks about replacing unhealthy acids conventionally contained in the food articles that are consumed by the children/adolescent/adults. Therefore it appears necessary to define that **food** as free of the unhealthy acids. Support for claim 43 may be found, for example, in the first full paragraph, page 14 of the PCT publication. Applicants believe the claim amendments and accompanying remarks herein serve to show the patentability of the present invention. No new matter has been added.

35 USC 112:

The Examiner raised an objection of lack of clarity against claim 25. In response, claim 25 has been canceled in favor of new claim 42. In this regard it is asserted that the categories "infant" and "child" are mutually distinct. According to medical dictionaries the term "infant" pertains to newborns up to the age of about 2 years or less. See below definition taken from web (From MedicineNet.com):

Definition of Infant

Infant: A child up to 2 years (24 months) of age.

The word "infant" came from the Latin *infans* which was derived from *in-*, not + *Fari*, to speak = not to speak, speechless. The idea was that, since the ability to speak was thought to arrive at the age of two, younger children were infants.

Claim rejections- 35 USC 102

Claims 25, 32, 34 and 36-37 were rejected as anticipated by InFat PR which only refers to infant formula, and by Spurgeon regarding its disclosure of Betapol, an infant food ingredient, namely, a human milk fat equivalent. Claim 25 has been replaced by new claim 42. The invention is a method and not a composition, and thus the method steps must be examined. Therefore, neither the InFat publication nor Spurgeon destroys the novelty of the invention defined in claims 42, 32, 33, 34, 36-39, 41 and 43.

It is respectfully submitted that in view of the current amendments to the claims, the rejection on the basis of anticipation no longer applies.

Applicants already have addressed the issue of the InFat Press Release and as the claims are clearly limited to other than infant formula. In the Press Release, InFat is mentioned only for infant formula, and therefore there is no anticipation. The examiner's reference to children as including infants is unsustainable according to accepted definitions.

It is respectfully submitted that in view of the current amendments to the claims, this objection becomes moot. The InFat PR publication only refers to infant formulas, which are excluded from the scope of the method claims.

In the action, it was stated that Betapol provides enhanced calcium retention. It is respectfully submitted that Spurgeon mentions nothing whatsoever about enhancement of absorption of dietary calcium. The article mentions that Betapol has a potential use as a fat source in infant formulae. The search investigated the effect of consumption of Betapol in rodents, not in humans, on general toxicity and particularly reproductive toxicity, developmental toxicity and development of reproductive organs, all of which have nothing to do with enhancement of absorption of dietary calcium.

Claim rejections- 35 USC 103

Inventive step in view of Spurgeon and Kennedy references

Claims 25, 31-34 and 36-40 were rejected under Sec. 103 as being obvious over Spurgeon et al., in view of Kennedy et al. Applicant respectfully traverses, for previously argued reasons and further more as follows:

The study of Spurgeon et al. is a study of the influence of consumption Betapol contained in regular chow, on the reproductive system of rodents. According to the study, Betapol had no adverse effect on the rodent reproductive system.

Kennedy is a study of the effect of, *inter alia*, Betapol, on stool biochemistry and characteristics and bone mineralization in formula-fed term infants.

It is respectfully submitted that it would not have been obvious for a man of ordinary skill in the art to use a fat base of the kind of Betapol in a food article other than infant formula, with the object of enhancing absorption of dietary calcium, bone formation and mass maximization.

Betapol was developed as a component of infant formulae, for infant nutrition, *inter alia* in order to solve the problem of formation of calcium soaps in the stool.

As also argued previously, one of the surprising aspects of the present invention is the novel use of InFat in food preparations that are different from infant formula. The function of the fat in the infant formula is for supplying nutritional basis, as a formula should supply all the necessary fatty acids with the correct balance between saturated, monounsaturated, polyunsaturated (such as omega-3 and omega-6) and its fat ingredient should as closely as possible mimic human milk fat.

In contrast, in the food industry there is a search for oils and fats according to their physical properties, i.e., their melting curve, to meet the needed physical properties of the manufactured food, as detailed in the response to the previous Office Action.

Without being repetitive, it is to be appreciated that food producers would have avoided the use of fats as ingredients of food articles, if the fats were not essential for obtaining the required physical properties mentioned. This is in contrast to producers of infant formulas, who are required to provide the fat as part of the nutrition of the newborn and as part of a replacement for breast feeding.

Thus, replacing an ingredient of a food product, like an oil or fat, which is aimed at obtaining a physical property of the food, with a nutritionally superior ingredient, that still confers the same final physical property, and thus providing additional nutritionally valuable characteristics, is not at all obvious.

A main concern of the food industry is the use of fats as additives to food products. Over-consumption of triglycerides through the diet, the presence of *trans* fatty acids and the content of total saturated fat are major issues, and it is important to limit the content of such ingredients due to their negative effects on health of the consumer, mainly on blood lipid balance, increased risk for CVD etc. The effect of calcium loss or reduction of calcium absorption due to the fatty acids positional distribution in a food product is not discussed and not part of the public awareness or in the food producers' agenda. Evidently, the labeling requirements of food products are for their total fat content and total saturated fat content. Lately, public awareness and legislation for the adding appropriate labeling regarding the *trans* fat content of a food article are increasing, however no attention given to the positioning of saturated fat content on the triglycerides in any food product.

Such improvements are achieved by the use of the present invention. As described in the application (paragraph bridging pages 12 and 13 of the international publication): "

.....It is a purpose of this invention to provide a dietary lipid ingredient that would ensure maximal calcium absorption and/or lack of inhibition of calcium absorption through the replacement of unhealthy oils and fats which promote the secretion of calcium, as well as other important minerals. Such oils and fats, characterized by relatively high degree of fatty acid saturation at the sn-1 and -3 positions are becoming more and more abundant in the diets of young children, adolescents and young people. The lipids of the invention, when consumed routinely in different food products or as dietary supplements together with mineral supplementation may increase the calcium intake and hence bone mass peak, resulting in a preventive condition to bone depletion disorders in later years of life."

No such use is described or suggested by Spurgeon and/or Kennedy, and would not be a result also of their combination.

The same is true for the combination of Spurgeon with the InFat PR.

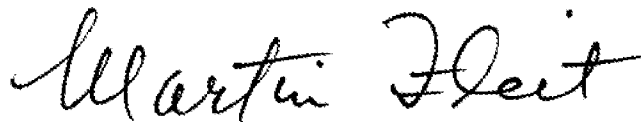
It is therefore respectfully submitted that the novel use of the invention is also not obvious in view of the cited documents, and is not taught or even suggested by the cited art. It is unlikely that a person skilled in the field of food products manufacturing would have used HMF mimic as a "healthy" replacement of conventional fat/oil ingredients, designed merely for obtaining desired physical features for the food product. The use of a synthetic, structured lipid fraction, mimicking the HMF that was developed and intended for a completely different use (infant nutrition) in order to replace vegetable oils due to their harmful characteristics, to which there has been no awareness in the food industry is novel, inventive and advantageous.

In light of the foregoing remarks, it is respectfully requested that the amended claims be reconsidered as this application should be in condition for allowance. Early passage of this case to issue is respectfully requested. If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be

appreciated since this should expedite the prosecution of the application for all concerned.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time, time sufficient, to effect a timely response, and shortages in this or other fees, be charged, or any overpayment in fees be credited, to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 7056-X08-022)

Respectfully submitted,

A handwritten signature in black ink that reads "Martin Fleit". The signature is written in a cursive, flowing style with a large initial 'M' and a distinct dot over the 'i' in 'Fleit'.

Martin Fleit, Reg. #16,900

FLEIT GIBBONS GUTMAN BONGINI & BIANCO
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: MFleit@Fggbb.com